4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3326]

Biosimilar User Fee Act; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled "Biosimilar User Fee Act; Public Meeting" that appeared in the <u>Federal Register</u> of September 19, 2016 (81 FR 64171). The document announced a public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2018 through 2022. The document was published with the incorrect date of the closure of the docket and incorrect transcript information. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115, lisa.granger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the <u>Federal Register</u> of Monday, September 19, 2016, in FR Doc. 2016-22442, the following corrections are made:

- On page 64172, in the first column, in the third sentence of the DATES section, "October 19, 2016" is corrected to read "October 28, 2016."
- 2. On page 64175, in the third column, the section "<u>Transcripts</u>: As soon as a transcript is available, FDA will post it at

2

http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm

." is corrected to read "Transcripts: Please be advised that as soon as a transcript is

available, it will be accessible at http://www.regulations.gov and

http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm

. It may be viewed at the Division of Dockets Management, Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be

available in either hardcopy or on CD-ROM, after submission of a Freedom of

Information request. The Freedom of Information office address is available on the

Agency's Web site at http://www.fda.gov."

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-23523 Filed: 9/28/2016 8:45 am; Publication Date: 9/29/2016]